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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,439	04/22/2005	Leslie Joe Dunaway	S-0828-A-US	9140

2071 7590 03/04/2010

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
03/04/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,439	DUNAWAY, LESLIE JOE	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-14* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 15-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments/Remarks and amended claims filed on 11/17/09 is acknowledged.

Claims 1-7 and 15-21 have been withdrawn. Claim 8 has been amended.

Claims 8-14 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 8-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Arneric (US PG pub. 2004/0235925 A1).

Arneric discloses a method for treating inflammation or an inflammation associated disorder in a subject in need of by providing atomoxetine and cyclooxygenase-2 selective inhibitor (see abstract).

The reference teaches treatment of inflammatory disorders such as asthma, see paragraph [0470] on page 45. The reference teaches Atomoxetine may be obtained from any source and refers to USP 4,314,081 for the preparation of atomoxetine. (Note: The reference USP 4,314,081 teaches using Atomoxetine HCl salt.). The reference teaches oral administration [0480] on page 46.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arneric (US PG pub. 2004/0235925 A1).

Arneric discloses a method for treating inflammation or an inflammation associated disorder in a subject in need of by providing atomoxetine and cyclooxygenase-2 selective inhibitor (see abstract).

The reference teaches treatment of inflammatory disorders such as asthma, see paragraph [0470] on page 45. The reference teaches Atomoxetine may be obtained

from any source and refers to USP 4,314,081 for the preparation of atomoxetine. (Note: The reference USP 4,314,081 teaches using Atomoxetine HCl salt.). The reference teaches oral administration [0480] on page 46. The reference teaches oral administration [0480] on page 46. The reference teaches in paragraph [0477] on page 46 that the administration of each agent that is atomoxetine and cyclooxygenase 2 inhibitor is in a **sequential** manner, can be taken together or taken within a period of time sufficient to provide beneficial effect. Prior art teaches sequential administration, it is therefore evident that atomoxetine by itself has therapeutic effect in treating disorders related to asthma, therefore administration of atomoxetine only, to treat disorders related to asthma would be obvious to one of ordinary skill in the art.

Response to Arguments

6. Applicant's arguments filed 11/17/09 have been fully considered but they are not persuasive.

Applicant argues that the cited reference does not mention asthma, and does not anywhere teach or suggest that atomoxetine, in the absence of any of the co-ingredient anti-inflammatory agents, could have any anti-inflammatory effect which could make one consider its use as the principal active ingredient in the treatment of asthma. Moreover, there is no evidence provided in the Office Action suggesting that NSAIDs in anyway are useful agents for the type of inflammation seen in asthma. Applicant believes that the only two types of agents previously found to be useful for the inflammatory component of asthma were corticosteroids and leukotriene inhibitors. See

in this connection, for example, the published article, "Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma," National Asthma Education and Prevention Program, NIH Publication No. 02-5074 (June 2003), attached hereto. Applicant adds that atomoxetine shares the same basic mechanism of action in the CNS on norepinephrine as venlafaxen and duloxetine, but there is no information of record that either of these two drugs has any effect on asthma. See further in this connection the published article, Moultry, M. et al., "The Use of Antidepressants for Chronic Pain," *U.S. Pharmacist* 7/20/2009 (as republished at http://www.medscape.com), attached hereto. Moreover, nothing in the cited reference or Office Action would explain how or why one might be motivated to select atomoxetine from amongst the available NRIs, to arrive at a treatment for asthma as claimed. According to applicant there is nothing of record to suggest that one of skill in the art of asthma treatment could infer from the sole applied reference that atomoxetine alone would or could be considered for use as the principal active ingredient in a treatment of asthma or allergy, without the benefit of Applicant's disclosure.

These arguments are not persuasive. In response to Applicant's arguments that there is no mention of asthma in the reference and the reference does not teach or suggest atomoxetine itself for the treatment of Asthma without the co administration of anti-inflammatory agents, the Examiner respectfully points out that the reference does teach treating inflammation associated disorders such as Asthma in paragraph [0470] on page 45. Paragraph [0471] emphasizes that the terms pain, inflammation-associated disorders are meant to include each of the symptoms or diseases that is mentioned

above that is in paragraph [0170] which discloses treating inflammation associated with Asthma. In response to applicants arguments that the reference does not teach administering only atomoxetine without co administration of anti-inflammatory agents, it is pointed out that the reference explicitly teaches in paragraph [0477] on page 46 that the administration of each agent that is atomoxetine and cyclooxygenase 2 inhibitor is in a **sequential** manner and can be taken together or taken within a period of time sufficient to provide beneficial effect. Prior art teaches sequential administration, it is therefore evident that atomoxetine by itself has therapeutic effect in treating disorders related to asthma, therefore administration of atomoxetine only, to treat disorders related to asthma would be obvious to one of ordinary skill in the art.

In response to applicant's arguments that the only two types of agents previously found to be useful for the inflammatory component of asthma were corticosteroids and leukotriene inhibitors as evident by the published articles, "Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma," National Asthma Education and Prevention Program, NIH Publication No. 02-5074 (June 2003), there is no information of record that either of these two drugs has any effect on asthma, the Examiner respectfully submits that the archive of references do not include any information regarding atomoxetine and since the prior art teaches treatment of inflammation associated disorders related to Asthma and sequential administration of atomoxetine, it would be apparent to one of ordinary skill in the art to provide oral administration of atomoxetine itself to subjects in need of treatment of inflammation related disorders caused due to asthma or in other words for treatment of asthma.

Applicants have not defined specific symptoms of asthma in the claims. The instant claims recite limitation as treating asthma not curing asthma, therefore, prior art's teachings of treating inflammatory related disorders caused due to asthma will read on the instant claims. The language of claims to "consisting essentially of "does not change the effect because prior art teaches administration of atomoxetine in sequential or co administration manner.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-

272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/
Examiner, Art Unit 1612
/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612